IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-2017 (RGA) (SRF)
	)	**CONSOLIDATED**
MSN LABORATORIES PRIVATE LIMITED	)	
and MSN PHARMACEUTICALS, INC.,	)	**REDACTED -- PUBLIC VERSION**
	)	
Defendants.	)	

LETTER TO THE HONORABLE SHERRY R. FALLON
REGARDING EXELIXIS' REQUEST TO MODIFY THE PROTECTIVE ORDER

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Attorneys for Plaintiff Exelixis, Inc.

Dear Judge Fallon:

Exelixis respectfully asks the Court to modify the Protective Order by adding a narrowly-tailored "Highly Confidential Information" designation, limiting four discrete categories of Exelixis trade secret and proprietary information to "Outside Attorney's Eyes Only" ("OAEO"). Such protection is common for highly confidential trade secrets—indeed, ***MSN has agreed to such protection of the exact same type of information in other cases***—and is warranted here. The trade secrets at issue include Exelixis' process for making its commercial products, including how it obtains high purity Form N-2 (a particular polymorph of the active ingredient cabozantinib), and detailed late-stage drug product manufacturing process steps and controls.[1] None of this extremely detailed technical information is relevant to the patent issues in the litigation. Nor is it necessary for MSN's U.S. Regulatory Agent to see this information in order to provide meaningful input on litigation strategy. Moreover, even inadvertent use or disclosure of such information would pose serious harm to Exelixis. While MSN opposes this motion, MSN has identified no concrete need for its U.S. Regulatory Agent to access this trade secret information. Indeed, MSN litigated this case for nearly two years without seeking in-house access to these trade secrets. The Court's July 14 Order, (D.I. 162), issued over Exelixis' objection, granted MSN's in-house, non-lawyer representative access to vast amounts of Exelixis' confidential information produced in this litigation. Exelixis' instant request to further amend the Protective Order in view of that order is justified, and also entirely consistent with the rationale of the Court's prior decision.

I. Background Information

The Parties' Dispute. The parties entered a stipulated Protective Order on December 6, 2019 (D.I. 12). The Protective Order permits each side to designate an in-house attorney or legal personnel to receive an opposing party's "Confidential Information." On July 14, over Exelixis' objection, the Court permitted MSN to designate Dr. Kondal Bairy as its in-house representative even though he is not a lawyer or legal personnel,[2] but a Ph.D.-trained medicinal chemist who is MSN's only U.S.-based employee. In this role, he acts as MSN's U.S. Regulatory Agent, responsible for regulatory strategy and gaining FDA approval for generic cabozantinib. The Court overruled Exelixis' objection in part in view of another MSN case (*Intercept Pharms., Inc. v. Apotex, Inc.*) that allowed a non-legal representative from MSN to review documents under that case's protective order. *See* D.I. 162 at 5. Notably, that protective order had two tiers of confidentiality designations, including an upper-tier for OAEO information. *Intercept Pharms, Inc. v. Apotex, Inc.*, C.A. No. 20-1105, D.I. 56 at 4, 13 (D. Del. Apr. 26, 2021) (Ex. E).

Since the July 14 Order, Exelixis and MSN have met and conferred several times regarding Exelixis' request to further modify the Protective Order, to likewise include an upper tier of "Highly Confidential Information." *See* Ex. C. Under the proposal, MSN's representative, Dr. Bairy, would retain access to Confidential Information—the vast majority of information produced in this case—but he would not have access to a limited category of Highly Confidential Information. While MSN and Exelixis have agreed to include an upper tier, the parties have not been able to agree on the definition of "Highly Confidential Information." In particular, MSN

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[1] Exelixis also seeks to protect non-public proprietary information relating to cabozantinib forms not at issue in this case ("Other Cabozantinib Forms").

[2] Before becoming MSN's regulatory agent, Dr. Bairy worked in MSN's chemistry labs. As a result, he is a named inventor on MSN patent applications concerning compound manufacturing. By contrast, Exelixis' in-house designee is a lawyer with no technical background or patents.

does not agree that the definition should include the following:[3]

> [i] Exelixis' non-public processes for making cabozantinib forms, [ii] its methods, techniques, or controls used to prevent or identify conversion from one form to another, [iii] its performance data for the different cabozantinib forms, and [iv] its non-public information for cabozantinib forms other than the L-malate salt.

The Exelixis Trade Secrets and Proprietary Information Sought to be Protected. Exelixis has invested [redacted] in the research and development of cabozantinib. Ex. M. Dozens of chemists and biologists spent years experimenting with thousands of compounds before cabozantinib was discovered in 2003. Ex. B at ¶ 4. Even after identifying cabozantinib's chemical structure, Exelixis invested additional resources to develop a consistent and reproducible method to manufacture a stable form of cabozantinib on a commercial scale. *Id.* To achieve these goals, Exelixis experimented with creating different forms of cabozantinib, including multiple salt forms. *Id.* During this experimentation, Exelixis learned that the preferred (L)-malate salt form was polymorphic, existing in two distinct crystalline forms, later named Form N-1 and Form N-2, with N-2 identified as having preferred qualities. *Id.* at ¶¶ 5-7.

During subsequent clinical and commercial development, the FDA required that Exelixis develop methods and controls to ensure that its cabozantinib products [redacted] *Id.* at ¶ 7. Exelixis spent years and many millions of dollars doing so, as this work was significantly more complex than is typical in an NDA. *Id.* at ¶ 9. Perfecting these proprietary manufacturing methods required careful development of a tailored process and related methods for analyzing the performance of different cabozantinib forms, including how the forms performed under various conditions. *Id.* at ¶ 7. In addition, Exelixis studied how Other Cabozantinib Forms affected the properties of the drug. *Id.* at ¶ 4. This information relates to Exelixis' development of the best method for manufacturing Form N-2 and controlling for it over N-1. *Id.* at ¶ 7. As explained in the in the Declaration of Dr. Khalid Shah, Exhibits H, I, J, and K are representative of the four categories (the "Representative HCI Information"). "Highly Confidential Information" is indicated for redaction by red boxes.

The Patent Issues in This Case. None of the four patents-in-suit (U.S. Patent Nos. 7,579,473; 8,497,284; 8,877,776; and 9,809,549) relate to the above-described manufacturing or formulation issues. Rather, the patents claim the novel cabozantinib compound, methods of using the compound in treating certain types of cancer, and two crystalline forms of the (L)-malate salt of cabozantinib (N-1 and N-2).

MSN's Cabozantinib-Related Products. [redacted]

II. Argument

There is good cause to modify the Protective Order to include Exelixis' proposed definition of Highly Confidential Information. *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). MSN has agreed to similar language in other cases. There is no reason in this case that

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[3] MSN otherwise has agreed to modify the protective order as seen in Ex. A. *See* Ex. C at 7.

MSN's U.S. Regulatory Agent needs to see Exelixis' detailed, confidential manufacturing information to provide oversight and input on litigation strategy. Moreover, given that MSN is in the business of [redacted], disclosure of this information to MSN presents an undue risk to disclosure of highly confidential and proprietary information.

The Highly Confidential Designation is Focused on Protecting Exelixis Trade Secrets. Exelixis' proposed "Highly Confidential" designation is narrowly tailored to protect a discrete set of trade secret information concerning Exelixis' process for manufacturing Form N-2 as well as non-public information regarding Other Cabozantinib Forms. For example, as reflected in the Representative Documents, the information sought to be protected relates to the particular methods Exelixis uses to manufacture cabozantinib L-malate. Ex. B at ¶¶ 7-8. As described in the Shah Declaration, this information is non-public, and, given the years of work done to develop it, highly valuable to Exelixis. *Id.* at ¶ 9. Among the research challenges, cabozantinib salts showed a tendency for polymorphism—i.e., they may unexpectedly form different crystalline forms—and conversion. These changes in form can affect stability, solubility, and cause clinically significant differences in efficacy and safety. Exelixis explored these tendencies and developed a proprietary method of controlling the form in Exelixis' cabozantinib products. *Id.* at ¶¶ 7-9. Such trade secret information is commonly protected from in-house disclosure in Hatch-Waxman patent litigation, ***including cases where MSN was a party***. But unlike those other cases ***where MSN has agreed to OAEO treatment***, the category of information sought to be protected by Exelixis here is far ***narrower and specifically tailored***. *See Biogen Int'l GmbH v. Amneal Pharms. LLC*, C.A. No. 17-823, D.I. 63 at 3-4, 16 (D. Del. Feb. 8, 2018) (MSN and 23 other generic defendants agreeing to designate ***entire NDA*** and non-public API characterization, manufacturing, and process information as OAEO) (Ex. F); *see also Takeda Pharm. Co. v. Actavis Labs. FL, Inc.*, C.A. No. 15-451, D.I. 26 at 3, 9-10 (D. Del. Oct. 28, 2015) ("sensitive proprietary data . . . and sensitive trade secrets" limited to OAEO.) (Ex. G).[4]

Disclosure of the Trade Secrets to MSN Would Harm Exelixis. Documents, testimony, and data reflecting this work is highly sensitive because generic competitors such as MSN are likely to face the same challenges in developing their own cabozantinib products. As a result, were inadvertent disclosure to occur, the trade secrets could be leveraged in the development of competing products. For example, a competitor developing a N-2 product [redacted] would find highly valuable the Representative HCI Information because it would aid in developing a consistent and reproducible method of making the N-2 form of cabozantinib, including by minimizing conversion to Form N-1. Although the Court has determined that Dr. Bairy is not a "competitive decision-maker," that is not dispositive to the issue presented here as protective orders commonly include a heightened level of protection for certain categories of information ***even though the disclosed recipients are not competitive decision-makers***. *See e.g.*, Ex. E at 13 (including an OAEO tier even though in-house disclosure of confidential information is limited to in-house lawyers). Notwithstanding an individual's "great moral fiber," courts "dress technical information with a heavy cloak of judicial protection because of the threat of serious economic injury to the discloser of scientific information." *Safe Flight Instrument Corp. v. Sundstrand Data Control, Inc.*, 682 F. Supp. 20, 22 (D. Del. 1998).

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[4] In this case as well, there is a history of treating certain types of information as OAEO. For example, MSN previously argued that its own nonpublic polymorph projects should be produced only to outside counsel. (Feb. 23, 2021 Transcript at 52:18-53:02 (Ex. L).)

MSN Cannot Establish Prejudice. MSN has not and cannot identify any legitimate need for its in-house designee, Dr. Bairy to have access to this limited category of Exelixis' trade secret information. During the meet and confer process, Exelixis provided MSN's outside counsel with proposed redacted versions of two of the Representative Documents. Ex. C at 9-10 MSN only pointed to three issues reasons for Dr. Bairy to have access, none of which is defensible.

First, MSN argued that the redacted information is relevant to obviousness because it shows that the patented forms were supposedly the "natural result of ordinary" experiments and that Exelixis had to develop methods to prevent "the alleged inventive crystals from forming." Ex. C at 3. But that is incorrect and, in any event, misunderstands the law: Exelixis' internal, non-public information is not prior art, so it cannot support an obviousness finding. *See Invitrogen Corp. v. Biocrest Mfg.*, 424 F.3d 1374, 1380-81 (Fed. Cir. 2005). Moreover, the "inventor's own path itself never leads to a conclusion of obviousness; that is hindsight." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

Second, MSN contended that the proposed redactions "cover[ed] experiments and analysis related to MSN's contention that claims of the '549 patent are invalid under 35 U.S.C. § 112 because the specification does not disclose any meaningful differences between Compound (I), Form N-1 and Compound (III), Form N-1." Ex. C at 3. Aside from being vague and entirely unspecific, MSN acknowledges that its Section 112 argument depends on what the "***specification***" discloses (as it must), not Exelixis' internal data. *Id.*

Third, MSN suggested that the information may be relevant to rebut Exelixis' infringement theory. Exelixis contends that [redacted] to a claimed form (e.g., N-2 or N-1). But the Exelixis trade secret information does not relate to conversion from [redacted] rather it relates to conversion ***from Form N-2***. And MSN says Exelixis' "processes . . . [redacted] Ex. C at 3—so it is unclear how information about ***Exelixis'*** process would be relevant to ***MSN's*** infringement. Furthermore, as Exelixis proposed several times during the meet and confer process, to the extent that any of its experts affirmatively rely on Exelixis trade secret information in connection with forming an opinion in this case, then Exelixis is willing to include a clause in the Protective Order that would allow for the information to be de-designated as appropriate. Ex. C at 18-19. MSN declined.

Finally, even if MSN could show that Exelixis' manufacturing development and processes have some tangential relevance to this case, ***that by itself does not establish that its U.S. Regulatory Agent needs access to all of the most highly confidential documents***. MSN has offered no reason why Dr. Bairy cannot properly advise on litigation strategy while relying on MSN outside counsel, in conjunction with its retained experts, to conduct the direct review of Exelixis' trade secret information. In fact, MSN's own actions prove that Dr. Bairy does not require these documents to manage the case. MSN itself waited twenty months before seeking such access. During this time period, MSN developed its core case theories, preparing invalidity contentions, non-infringement contentions, and other interrogatory responses. MSN also served all of its offensive discovery. If MSN truly required Dr. Bairy's access to the trade secrets, MSN would have sought it long ago. *PhishMe, Inc. v. Wombat Sec. Techs., Inc.*, C.A. No. 16-403, 2017 WL 4138961, *2 (Sept. 8, 2017) (Burke, J.) (no demonstrable need for access to OAEO material where case was litigated for 10 months).

For these foregoing reasons, Exelixis respectfully requests that the Court grant its request.

Respectfully submitted,

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

Enclosures

cc: All Counsel of Record (w/enc.)